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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/514,113 | 02/28/2000 | Frank B. Dean | MSI 100 | 9257 |

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ATLANTA, GA 30303-1811

EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 08/12/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/514,113

Applicant(s)

DEAN ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2002 and 24 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,21-23,27,31-45 and 50-80 is/are pending in the application.
- 4a) Of the above claim(s) 50-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19,21-23,27,31-45 and 77-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634.

Claim Objections

2. Claim 21 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21 depends from canceled claim 20.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-19, 21-23, 27, 31-45, and 77-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 1, 21-23, 44, 45, 77, 79, and 80 provides for the use of template deficient oligonucleotides, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim

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is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Claims 2-19, 27, 31-45, and 78, which depend from independent claims 1, 23, 77, 79 and 80, fail to overcome this issue and are similarly rejected.

6. Claims 1-19, 21-23, 27, 31-45 and 77-80 are is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

7. Claim 78 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 78 is indefinite, as it does not end with a period. Accordingly, the metes and bounds cannot be readily determined.

8. Claims 77 and 80 recite the limitation "the two or more adjacent template-deficient nucleotides" in line 6. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1, 5, 8-10, 198, 22, and 77 are rejected under 35 U.S.C. 102(a), (e) as being anticipated by Wallace (US Patent 6,027,923).

11. Wallace, columns 9 and 10, disclose the use of primers that contain a non-replicable element wherein said primers are used in a nucleic acid amplification reaction. Figures 3-5 show that the modified nucleotide is located several bases upstream, or 5', to the template capable portion of the primer.

12. Wallace, column 9, third and fourth paragraphs, disclose the use of abasic nucleotides in primer used in an amplification reaction. The teaching of "primers that contain non-replicable and/or cleavable elements" (column 9, lines 18-19) has been interpreted as there being a plurality of such nucleotides in a primer. Also, column 9, lines 32-33, teaches the presence of "a residue" in a primer. Accordingly, Wallace is considered to teach the use of one or more such abasic nucleotides.

Response to argument

At page 12 of the response received 06 September 2002 argument is advanced that Wallace does not anticipate the claimed invention. As set forth at page 12:

[O]ne of the properties of any primer of claim 1 is that the sequence of the template-deficient oligonucleotide 3' of the template-deficient oligonucleotide is sufficient both in terms of the composition and number of nucleotides to hybridize effectively to the sequence of the template strand provided and to effectively prime synthesis. However,

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the primers of Wallace are specifically designed to be, and are required to be, incapable of effectively priming nucleic acid synthesis in the nucleic acid amplification reaction where only the sequence 3' to the non-replicable element is present with complementary sequence. This follows from the goal of Wallace to prevent replication of second-generation primer extension products.

The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. Upon review of Wallace at column 2, it is abundantly clear that the primers disclosed in the prior art both contain a nucleotide that is "template deficient" yet are used in repeated rounds of amplification. It is clear that both first and second-generation primer extension products are generated; see column 2, lines 44-48. As stated therein:

[T]reating the first generation primer extension products with the primers of step (a) under conditions such that second generation primer extension products are synthesized using the first generation primer extension products as templates.

Claim 1 specifically requires that "the number and composition of template-capable nucleotides 3' of the template-deficient nucleotide closest to the 3' end of the template-deficient oligonucleotide [be] sufficient to allow the template-capable nucleotides 3' of the template-deficient nucleotide closest to the 3' end alone to effectively prime nucleic acid synthesis."

Given that the template-deficient nucleotides disclosed by Wallace are the same as that contemplated by applicant, it stands to reason that the template-deficient nucleotides in the template-deficient primer taught in the prior art are no more capable of priming than are the same primers of applicant. Basis for this position is taken on the principle that a compound and its properties are inseparable. Accordingly, the disclosure of Wallace is considered to anticipate the above-identified claims.

Claim Rejections - 35 USC § 102/103

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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17. Claims 1-19, 21-23, 27, 31-45 and 77-80 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Van Ness et al.

18. Van Ness et al., at columns 82-85 disclose performing amplification reactions where one or more abasic nucleotides are incorporated into a primer. As seen in TABLE 14, at least one of the primers contained modified nucleotides located at the 5' terminus, other primers contained modified nucleotides within three nucleotides of the 5' terminus. Column 84 depicts several of the primer sequences. As seen therein, different modified nucleotides were incorporated in the primers.

19. In view of the above showing, and in the absence of convincing evidence to the contrary, the disclosure of Van Ness et al., is considered to meet the limitations of claims 1-19, 21-23, 27, 31-45 and 77-80.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

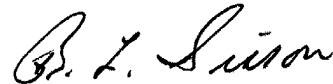
21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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22. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
August 7, 2002